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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/046,575	01/16/2002	Nishizumi Nishimuta	018995-452	4939

7590 12/16/2008  
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EXAMINER
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FAY, ZOHREH A

ART UNIT	PAPER NUMBER
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1612

MAIL DATE	DELIVERY MODE
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12/16/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/046,575	<b>Applicant(s)</b> NISHIMUTA ET AL.	
	<b>Examiner</b> ZOHREH A. FAY	<b>Art Unit</b> 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 13-30 is/are pending in the application.
- 4a) Of the above claim(s) 15-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 13, 14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

Art Unit: 1612

Claims 1, 13 and 14 are presented for examination.

The amendments, declarations and remarks filed on September 15, 2008 have been received and entered.

Claims 1, 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goodman et al. (WO 98/27960) in view of Fleischer (1999, abstract only); or Fleischer (1999) and Miller et al. (1980, abstract only) and further over Canadian Patent 2161737 (submitted by the applicant) for the reasons set forth on pages 2-6 of the office action of May 14, 2008 and the following reasons.

The Application for Canadian patent teaches the use of a topical formulation of metronidazole at the concentrations of 1% cream, 0.75% topical gel and 5% topical suspension for the treatment of inflammatory skin conditions. See Page 1. The above reference makes clear that metronidazole has been previously used at the claimed range concentrations.

Applicant's arguments and remarks have been carefully considered, but are not deemed to be persuasive for the reasons discussed in the previous office action and the following reasons. Applicant in his response presents declarations to show the concentration of 0.75% of metronidazole for the treatment inflammatory papules and pustules rosacea. Applicant argues that the exhibits do not teach the use of metronidazole for the treatment of atopic dermatitis. Applicant further argues that the highest concentration of metronidazole used by Curatek pharmaceuticals, Inc. is 1%. Applicant continues by saying that one skilled in the art would not have been motivated to use metronidazole at the claimed concentrations of 1.5-5% for the topical skin

Art Unit: 1612

disorders. The arguments in view of the newly relied upon reference, the application for Canadian Patent 2161737, which teaches the concentration as high as 5% of metronidazole topically for the treatment of inflammatory skin disorders are not considered to be persuasive.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ZOHREH A. FAY whose telephone number is (571)272-0573. The examiner can normally be reached on Monday to Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fredrick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ZF  
/Zohreh A Fay/  
Primary Examiner, Art Unit 1612

Application/Control Number: 10/046,575  
Art Unit: 1612

Page 4